



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460 Form

Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and .025 hours per response for information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to the address.

DATA MATRIX – INTERNAL USE VERSION

Date: August 9, 2022		EPA Reg No./File Symbol: 11556-155		Page 1 of 8		
Elanco US Inc. Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390		Product: <i>PNR1427 Insecticide (syn. Seresto)</i>		Ingredient: Flumethrin (CAS 69770-45-2 ) Imidacloprid (CAS 138261-41-3)		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Report Number	Comments

*PNR 1427 Insecticide End-Use Product Specific*

Product Chemistry, Section 158.240						
830.1550	Product identity and Composition	48240101	11556	OWN	33752	
830.1600	Description of materials used to produce the product	48240101	11556	OWN	33752	
830.1620	Description of production process	48240101	11556	OWN	33752	
830.1650	Description of formulation process	48240101	11556	OWN	33752	
830.1670	Discussion on formation of impurities	48240101	11556	OWN	33752	
830.1700	Preliminary analysis					N.A. TGAI Only
830.1750	Certified of limits	48240101	11556	OWN	33752	
830.1800	Enforcement method	48240101	11556	OWN	33752	
830.1900	Submittal of samples					Samples available upon request
830.6302	Color	48240101	11556	OWN	33752	
830.6303	Physical state	48240101	11556	OWN	33752	
830.6304	Odor	48240101	11556	OWN	33752	
830.6313	Stability					N.A. – TGAI Only
830.6314	Oxidizing / reducing action					N.A.– EP not contain an oxidizing or reducing agent
830.6315	Flammability					N.R. – This product is not considered a combustible liquid, because the closed up flashpoint for all the ingredients is > 199°F.
830.6316	Explosibility					N.R. – This product does not contain any explosive ingredients.
830.6317	Storage stability	48416501	11556	Own	33906	Submitted 3/11/2011
830.6319	Miscibility					N.R. – This product is not an emulsifiable type
830.6320	Corrosion characteristics					Available 3/31/2011



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830.6321	Dielectric breakdown volt					N.A. – Not intended use around electrical equipment
830.7000	pH					N.A. – product not soluble in water and therefore pH not required.
830.7050	UV/Visible absorption					N.A. – TGAI Only
830.7100	Viscosity					N.A. – This product is a solid and viscosity is not applicable.
830.7200	Melting point					N.A. – TGAI Only
830.7220	Boiling point					N.A. – TGAI Only
830.7300	Density, bulk-density, or specific gravity					
830.7370	Dissociation constant in water					N.A. – TGAI Only
830.7520	Particle size, fiber length, and diameter distribution					N.A. – Nonfibrous product
830.7550 830.7560 830.7570	Partition coefficient (n-octanol/water)					N.A. – TGAI Only
830.7840 830.7860	Water solubility					N.A. – TGAI Only
830.7950	Vapor pressure					N.A. – TGAI Only
<b>Toxicology, Section 158.500</b>						
870.1100	Acute oral toxicity - rat	48240102	11556	OWN	33854	Waiver request
870.1200	Acute dermal toxicity	48240103	11556	OWN	33855	Waiver request
870.1300	Acute inhalation toxicity - rat	48240104	11556	OWN	33856	Waiver request
870.2400	Primary eye irritation – rabbit	48240105	11556	OWN	33857	Waiver request
870.2500	Primary dermal irritation	48240106	11556	OWN	33749	
870.2600	Dermal sensitization	48240107	11556	OWN	33750	
870.6100	Delayed neurotoxicity (acute) - hen					N.R. – Not an organophosphate
870.6200	Acute neurotoxicity - rat					N.R. – Not an organophosphate
870.3100	90-day oral - rodent					N.R.



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870.3200	21-day dermal - rabbit/rat					N.R. – Non-food use
870.3250	90-day dermal					N.R. – Collar not affect uptake
870.7200	Companion animal safety	48240108	11556	OWN	33800	Adult cat safety study
		48240108	11556	OWN	33826	Amendment 1 to adult cat study 33800
		48674702	11556	OWN	33968	Amendment 2 to adult cat study 33800
		48240109	11556	OWN	33805	Adult dog safety study
		48674701	11556	OWN	33967	Amendment to Adult Dog Study
		48240110	11556	OWN	33806	Puppy safety study
		48240111	11556	OWN	33824	Kitten safety study
		48240112	11556	OWN	33822	Reflector study (puppy)
		48240113	11556	OWN	33823	Reflector study (kitten)
		48240114	11556	OWN	35986	Reflector study (adult cat)
		48240115	11556	OWN	35637	Reflector Study (adult dog)
Product Performance, Section 158.400						
810.3300	Treatments to control pests of humans and pets					
		48240116	11556	OWN	33801	Fleas and ticks (dogs)
		48240117	11556	OWN	33802	Fleas and ticks (cats)
		48240118	11556	OWN	33803	Efficacy with bathing and water immersion against ticks and fleas
		48240119	11556	OWN	35630	Fleas and ticks [Ixodes ricinis] (cats)
		48240120	11556	OWN	35631	Adult and larvacidal flea control; repellency and tick control (dogs)
		48240121	11556	OWN	35635	Adult and larvacidal fleas, ticks study (cats)
		48240122	11556	OWN	35644	Field studies – fleas and ticks (cats)
		48240123	11556	OWN	35645	Field studies– fleas and ticks (dogs)
	Treatments to control pests of pets (cont’d)	48240124	11556	OWN	35980	Speed of kill for fleas (cats)
		48240125	11556	OWN	35987	Speed of kill for fleas (dogs)



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Report Number	Comments

		48240126	11556	OWN	33464	Ixodes Bridging study
		48240127	11556	OWN	35981	Ticks [Ixodes ricinis] (cats)
		48240128	11556	OWN	35979	Ticks [Ixodes ricinis] (dogs)
		48240129	11556	OWN	35982	Repellency and control of ticks (dogs)
		48240130	11556	OWN	33467	Juvenile Ticks
		48240131	11556	OWN	33694	Lice (Trichodectes canis)
		48240132	11556	OWN	33691	Sarcoptic mange
		48240133	11556	OWN	36172	Hair clipping study – Repellency and efficacy
		48240134	11556	OWN	15962	Hair clipping study
		48240135	11556	OWN	35642	Serum and haircoat kinetics in cats
		48240136	11556	OWN	35643	Serum and haircoat kinetics in dogs
		48240137	11556	OWN	15749	Advantage Efficacy against C. canis
		48576501	11556	OWN	33916	Ticks [Ixodes scapularis] ( <i>In vitro</i> ; dog hair)
		48576502	11556	OWN	33935	Ticks [Ixodes scapularis] (dogs)

Miscellaneous

None	Benefits Document (In the Public Interest)	48240138	11556	OWN	33860	Submitted w/ Flumethrin Technical Application
None	ORE Risk Assessment	48240139	11556	OWN	33861	
None	Release Rate Compilation	48240140	11556	OWN	35992	
None	Soluble Surface Content of Collar	48240141	11556	OWN	35118	
None	Formulation and Release Information (Lunchick)	50140801	11556	OWN	44722en	Submitted in response to RR Scoping Doc.
None	Determination of Exposure (Krudewagon)	50140802	11556	OWN	35122ene	Submitted in response to RR Scoping Doc.
None	Investigation of Composition after Abrasion (Jiritschka)	50140803	11556	OWN	37090	Submitted in response to RR Scoping Doc.
None	Flumethrin Release by Torsion stressing (Hammer)	50140804	11556	OWN	44739	Submitted in response to RR Scoping Doc.
None	Stroke Study on Dogs	49907401	11556	OWN	35120ene	Submitted in response to RR Scoping Doc.
None	Stroke study on Cats	49907402	11556	OWN	35121ene	Submitted in response to RR Scoping Doc.



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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status			
					Report Number	Comments	

None	Release & Transfer Discussion Document (Imidacloprid & Flumethrin)	50568001	11556	OWN	46001en	Submitted in response to HED request
None	Human Case Assessment Critique 2016_08_19	NA	11556	OWN	NA	Submitted 19AUG2016
None	Seresto Animal Assessment Bayer 2016_09_02 final	NA	11556	OWN	NA	Submitted 02SEP2016
None	Seresto® PV Internal Investigation 20MAR2021	51556601	11556	OWN	NA	Submitted 02MAY2021
None	Review of Serious Veterinary Adverse Event Reports for Seresto® Flea and Tick Collars for Cats and Dogs (2013-2015)	51556602	11556	OWN	NA	Submitted 02MAY2021
None	Review of Human Adverse Event Reports Involving Seresto®	51556603	11556	OWN	NA	Submitted 02MAY2021
None	Seresto® PV Internal Investigations 2018 – 2020	51567301	11556	OWN	NA	Submitted 14MAY2021
None	Addendum to Kingston Review of Human Adverse Event Reports	51567302	11556	OWN	48164	Submitted 14MAY2021
None	Cyton Seresto White Paper	51567303	11556	OWN	48167	Submitted 14MAY2021
None	Target Animal Safety with a 10% Imidacloprid + 4.5% Flumethrin Collar with or without Reflector Clips When Applied Once to Adult Cats	51580501	11556	OWN	35638	Submitted 18MAY2021
None	Longterm Target Animal Safety of a Single Application of a 10% Imidacloprid + 4.5% Flumethrin Collar with Reflectors on Cats	51580502	11556	OWN	35984	Submitted 18MAY2021
None	Longterm Target Animal Safety of a Single Application of a 10% Imidacloprid + 4.5% Flumethrin Collar with Reflectors on Adult Dogs	51580503	11556	OWN	35985	Submitted 18MAY2021
None	Pharmacokinetics of Flumethrin in the Hair of Dogs after Application of a Collar Containing 10% Imidacloprid Plus 4.5% Flumethrin in Comparison to a Collar Containing 10% Propoxur Plus 2.25% Flumethrin (Kiltix Collar)	51580504	11556	OWN	33131	Submitted 18MAY2021
None	Risk assessment on skin and eye irritation and skin sensitization of the formulants	51580505	11556	OWN	46791	Submitted 18MAY2021



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None	User Risk Assessment, March 2011, Imidacloprid/Flumethrin Collar	51580506	11556	OWN	37534	Submitted 18MAY2021
None	ORE and Risk Assessment for Seresto Dog and Cat Collars Formulated with Imidacloprid and Flumethrin	51580507	11556	OWN	48088	Submitted 18MAY2021
None	PMRA: Correlation of case reports to the exposure of AI from Seresto collar	51580508	11556	OWN	48165	Submitted 18MAY2021
None	Child resistance of reflectors	51580509	11556	OWN	36121	Submitted 18MAY2021
None	Statement on safety observations in clinical studies for Seresto in cats and dogs	51580510	11556	OWN	48166	Submitted 18MAY2021
None	PSUR 60793	51582101	11556	OWN	60793	Submitted 19MAY2021
None	PSUR 60807	51582102	11556	OWN	60807	Submitted 19MAY2021
None	PSUR 61087	51582103	11556	OWN	61087	Submitted 19MAY2021
None	BAY Vq 1950 – Subchronic toxicity study in dogs on oral administration / supplementary study (13-week feeding study)	51582104	11556	OWN	08252	Submitted 19MAY2021
None	Flumethrin & Imidacloprid (c.n.: Flumethrin & Imidacloprid) Study for acute combination toxicity in rats	51582105	11556	OWN	25977	Submitted 19MAY2021
None	VICH Target animal safety study with Imidacloprid 10 % / Flumethrin 4.5 % collars in dogs	51582106	11556	OWN	33692	Submitted 19MAY2021
None	VICH Target animal safety study with Imidacloprid 10 % / Flumethrin 4.5 % collars in cats	51582107	11556	OWN	33697	Submitted 19MAY2021
None	Pilot Safety Evaluation of PNR 1427 Collars in 10-Week-Old Kittens	51582108	11556	OWN	33776	Submitted 19MAY2021
None	BAY Vq 1950 – Subchronic toxicity study in dogs with oral administration (13-week feeding study)	51585201	11556	OWN	08036	Submitted 23MAY2021



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None	Method for the LC-MS/MS determination of imidacloprid and flumethrin in cotton gloves	51585202	11556	OWN	35962	Submitted 23MAY2021
None	Dosage and Release of the Active Ingredients Over Time	51585203	11556	OWN	35992	Submitted 23MAY2021
None	Plasma pharmacokinetics of imidacloprid and flumethrin in dogs after topical treatment using a collar (Seresto®) containing 10% imidacloprid and 4.5% flumethrin with special regard to the first 7 days of use	51585204	11556	OWN	44762	Submitted 23MAY2021
None	Plasma pharmacokinetics of imidacloprid after single oral administration to dogs	51585205	11556	OWN	45266	Submitted 23MAY2021
None	Plasma pharmacokinetics of flumethrin after single oral administration to dogs	51585206	11556	OWN	45267	Submitted 23MAY2021
None	Seresto - Review of PMRA Assessment	51585207	11556	OWN	48168	Submitted 23MAY2021
None	Seresto Collar (Cats & Dogs) Case Review (Deaths: ABON Coded A & B)	51585208	11556	OWN	48173	Submitted 23MAY2021
None	Seresto® Collar Cats and Dogs (Imidacloprid and Flumethrin) Bayer Animal Health Response Document to PMRA Meeting of July 14 2016	51585209	11556	OWN	48179	Submitted 23MAY2021
None	Bayer Animal Health Critique of PMRA's Animal Incident Assessment for the Seresto® Collar 02 Sep 2016	51585210	11556	OWN	48180	Submitted 23MAY2021
None	Bayer Animal Health Critique of PMRA's Incident Assessment 19 Aug 2016	51585211	11556	OWN	48181	Submitted 23MAY2021



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None	Elanco Seresto 8-K	51585212	11556	OWN	48182	Submitted 23MAY2021
None	Animal Incidence Reporting Rate	51587401	11556	OWN	48188	Submitted 25MAY2021
None	Death Reports and Convulsions 2013 to 2020	51587402	11556	OWN	48189	Submitted 25MAY2021
None	Incidents by EPA Severity Code	51587403	11556	OWN	48190	Submitted 25MAY2021
None	IRR Calculations	51587404	11556	OWN	48191	Submitted 25MAY2021
None	Preferred Terms over 1 per 10,000 in 2020	51587405	11556	OWN	48192	Submitted 25MAY2021
None	Seresto Analysis Through End 2017	51587406	11556	OWN	48193	Submitted 25MAY2021
None	Seresto Overview Through Q2 2018	51587407	11556	OWN	48194	Submitted 25MAY2021
None	Global SMT Compilation 2013-2016	51587408	11556	OWN	48185	Submitted 25MAY2021
None	Global SMT Compilation 2017-2018	51587409	11556	OWN	48186	Submitted 25MAY2021
None	Global SMT Compilation 2019-2020	51587410	11556	OWN	48187	Submitted 25MAY2021
None	Disproportionality Analysis Report MAY 2021	51587411	11556	OWN	48195	Submitted 25MAY2021
None	FIFRA 6a2 Letter Rsp for Item 7	51587412	11556	OWN	48196	Submitted 25MAY2021
None	Review of Seresto® Flea and Tick Collar Cases Reported to Pet Poison Helpline (January 2013 - March 2021)	51978501	11556	OWN	NA	Submitted 09AUG2022
None	Seresto Collar (Cats & Dogs) Case Review	51979502	11556	OWN	NA	Submitted 09AUG2022

Signature

Jennifer Schofield, DVM, CPH  
Regulatory Affairs Principal Scientist